REMARKS

Of the 9 original claims, claims 3-9 have been withdrawn from consideration, claim 10 has been added, and claims 1-2 have been amended herein. Support for the new claim and amendments may be found in the original claims and throughout the specification, e.g., lines 1 to 15 on page 61 of the specification. Thus, no new matter is introduced by these amendments.

With this response, claims 1, 2, and 10 are now pending. Applicants do not believe that any fees are due at this time; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to this document, the Commissioner is authorized to deduct the fees from Howrey Simon Arnold & White Deposit Account No. 08-3038.

For the Examiner's convenience, a list of currently pending claims is attached at the end of this document.

Rejection under 35 U.S.C. §101

Claims 1-2 were rejected under 35 U.S.C. §101, because the claimed invention allegedly lacks utility. The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "probes as detection markers or for assisting in the isolation of full-length cDNAs or genes which would be used to make protein and optionally further usage to make the corresponding antibodies, isolation of homologous sequences, detection of gene expression such as in Northern blot analysis, and for numerous other generic genetic engineering usages [*sic*]." Office Action dated August 30, 2000, at page 6. However, the Examiner contends that none of these utilities constitute a "substantial" or "specific" utility as defined in the "Revised Interim Utility Guidelines Training Materials."

Applicants traverse this rejection. The Examiner's application of these "Interim Guidelines" ignores the presently disclosed utilities and contravenes well-established doctrines of utility developed in the courts.

It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). The present specification describes many objectives that are met by the present invention. In addition to the utilities described by the Examiner (quoted above), the claimed nucleic acid molecules are useful for determining the presence and/or identity of polymorphisms, measuring the level of an mRNA in a sample, determining the location of a corresponding DNA sequence on a physical or genetic map, probing for other molecules, generating primers, obtaining other nucleic acid molecules from the same species, obtaining related protein coding sequences, obtaining promoters and other flanking genetic elements, screening maize and soybean cDNA or genomic libraries, obtaining nucleic acid homologues, detecting and characterizing gene expression, *etc.* (*see e.g.,* Specification beginning at page 80, under heading "Uses of the Agents of the Invention").

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. §101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize other nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally

sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. §101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather, the Examiner attempts to undermine the existing utilities by stating, "these are non-specific uses that are applicable to nucleic acids and enzymes in general and not particular or specific to the nucleic acids and enzymes being claimed." Office Action dated August 30, 2000, at page 6. Further, "...no substantial utility has been established for the claimed subject matter." *Id.* In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Moreover, this position offends the sensibilities. For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

As noted above, the claimed nucleic acid molecules have many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid sequences exhibit the requisite utility under 35 U.S.C. §101.

The examiner also contends that the claimed nucleic acids lack utility because the glutamyl-tRNA reductase enzyme encoded by the claimed nucleic acids allegedly lacks a substantial and specific utility. This contention is incorrect. Glutamyl-tRNA reductase (GluTR) has a well established utility; it is an essential component of the tetrapyrrole biosynthetic pathway in plants. No explanation of the well-established utility of GluTR is required. *See Kridl v. McCormick*, 105 F.3d 1446, 1451, 41 U.S.P.Q.2d 1686, 1690 (Fed. Cir. 1997). Nevertheless, Applicants direct the Examiner's attention to the specification, and the references cited therein, which describe the utility of GluTR at, for example, page 2 line 21 to page 5 line 16. GluTR clearly has a substantial ("real-world") utility because it plays an important role in the biosynthesis of ALA (a precursor of chlorophyll). GluTR also clearly has a specific utility, i.e., it catalyzes the conversion of Glu-tRNA to glutamate 1-semialdehyde (GSA). Therefore, the contention that the claimed nucleic acids lack utility

because GluTR lacks utility is clearly incorrect and cannot support a rejection of the claimed nucleic acids.

Surprisingly, the Examiner notes that the credibility of the presently asserted utilities has not been assessed. Office Action dated August 30, 2000, at page 7. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...").

Here, the Examiner has not even attempted to meet this burden. Thus, the Examiner's admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification.

Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 1-2 under 35 U.S.C. §101 is incorrect and should be withdrawn.

IV. Rejections under 35 U.S.C. §112, 1st Paragraph

Claims 1-2 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification, because the claimed invention allegedly lacks utility (*i.e.* an invention with no utility cannot be enabled). This rejection has been overcome by the foregoing arguments regarding utility.

Moreover, the Examiner has not met the evidentiary burden required to impose an enablement rejection. A specification that discloses how to use the claimed invention "must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein." *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995), *quoting In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971) (emphasis in original). It is also well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991).

As discussed above, the present specification discloses how to use the claimed nucleic acid molecules (*e.g.*, determining the presence and/or identity of polymorphisms, measuring the level of an mRNA in a sample, determining the location of a corresponding DNA sequence on a physical or genetic map, probing for other molecules, generating primers, probes as detection markers or for assisting in the isolation of full-length cDNAs or genes

which would be used to make protein and optionally further usage to make the corresponding antibodies, isolation of homologous sequences, detection of gene expression such as in Northern blot analysis, obtaining other nucleic acid molecules from the same species, obtaining related protein coding sequences, obtaining promoters and other flanking genetic elements to such molecules, screening maize and soybean cDNA or genomic libraries, obtaining nucleic acid homologues, detecting and characterizing gene expression, *etc.*) The Examiner, however, has provided neither evidence supporting the rejection, nor any explanation of why the specification allegedly fails to enable such uses. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph, is incorrect and should be withdrawn.

V. Rejection under 35 U.S.C. §102

Claim 1 was rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Ilag *et al.*, (*Plant Cell* 6, 265-275, 1994). According to the Examiner, Ilag *et al.* describe a nucleic acid sequence encoding glutamyl-tRNA reductase that displays some local similarity to the presently claimed sequence.

For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 U.S.P.Q.2d 1315, 1317 (Fed. Cir. 1988).

Applicants contend that Ilag *et al.* do not teach every element of the claimed

invention. According to the Examiner, Ilag *et al.* describe sequences that are 69.1% similar to SEQ ID NO: 586; 63.0% similar to SEQ ID NO: 590; 64.8% similar to SEQ ID NO: 594; 70.1% similar to SEQ ID NO: 596; 70.8% similar to SEQ ID NO: 597; 62.4% similar to SEQ ID NO: 599; 65.6% similar to SEQ ID NO: 600; 65.4% similar to SEQ ID NO: 601; 69.1% similar to SEQ ID NO: 604; 69.7 % similar to SEQ ID NO: 605; and 54% identical to SEQ ID NO: 650. However, Ilag *et al.* only describe *Arabidopsis thaliana* sequences, while the present claims are directed to maize and soybean sequences. Thus, Ilag *et al.* do not teach all of the elements of the present claims. Accordingly, Applicants request that the rejections of claim 1 under 35 U.S.C. §102(b) be withdrawn.

The Examiner is encouraged to contact the undersigned at (202) 383-6799 should any additional information be necessary for allowance.

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Currently Pending Claims for USSN 09/233,218

1. A substantially purified nucleic acid molecule that encodes a maize or soybean tetrapyrrole pathway enzyme or fragment thereof, wherein said maize or soybean tetrapyrrole pathway enzyme is a glutamyl-tRNA reductase enzyme.

2. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule comprises a nucleic acid sequence selected from the group consisting of SEQ ID NOS: 586, 590, 594, 596, 597, 599, 600, 601, 604, and 605.

10. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 90% identity with a sequence selected from the group consisting of SEQ ID NOS: 586, 590, 594, 596, 597, 599, 600, 601, 604, and 605.